

510(k) Summary**Trade Name: Vascutek Graft Sizer Set****Common Name: Graft Sizer****December 6, 1995**

The Vascutek Graft Sizer Set consists of nine individual double-ended 'C' shaped graft sizers. The nine sizers are secured within a clip and are available in a size range from 5 to 32 mm. The graft sizers are supplied sterile and are for single use only.

The Vascutek Graft Sizer Set is designed to aid the surgeon in accurately matching the size of vascular graft to the artery. The size of graft to be selected will correspond with the number indicated on the graft sizer which best fits the outside of the vessel.

Biocompatibility tests conducted on the finished device showed that the material is non-hemolytic, non-cytotoxic, and non-pyrogenic. In addition, extensive biocompatibility testing conducted on the material demonstrates its suitability for medical uses in devices and packaging. In addition, it has been shown that the material meets the requirements of USP Class VI-50, being compatible with blood and demonstrating no cytotoxic, mutagenic, or irritant potential.

CarboMedics considers the Vascutek Graft Sizer Set to be equivalent in intended use, composition, design, and function to the Meadox Graft Sizer manufactured by Meadox Medical, Inc. Marketing clearance was granted by the FDA for 510(k) number K854431 on May 7, 1986, for the Meadox Graft Sizer.

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